Clin. Lab. 2026;72:XXX-XXX
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SHORT COMMUNICATION

Internal Quality Control Monitoring for Alternate Erythrocyte Sedimentation Rate Testing

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ABSTRACT

Background: **Ensuring reliable quality control (QC) is essential for accurate ESR measurement in clinical laboratories.**
Methods: **This study evaluated the QC performance of the upgraded Alifax TEST1 2.0 (Alifax, Polverara, Italy). Within run and between-run precision was evaluated in accordance with the International Council for Standardization in Hematology using Alifax Latex quality control material and/or patient samples. A statistical moving average was established from 300 ESR patient samples referred for routine analysis.**
Results: **TEST1 2.0 demonstrated precision within the manufacturer's limits at low, middle and high ESR levels with quality control material. The precision of patient samples in the ESR range > 20 mm/hour was < 2.7%. The statistical moving average was 68.0 ± 8.3 mm/hour with a % coefficient variation of 12.2%.**
Conclusions: **Monitoring QC using latex QC materials in conjunction with a patient-based moving average, effectively monitors ESR, ensuring consistent performance and analytical confidence in routine ESR testing.**
(Clin. Lab. 2026;72:xx-xx. DOI: 10.7754/Clin.Lab.2025.251206)

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Short Communication accepted December 8, 2025

KEYWORDS

internal quality control, ESR, Test 1, statistical moving average

INTRODUCTION

The erythrocyte sedimentation rate (ESR) is a non-specific screening test for inflammatory and malignant disorders [1]. Historically, the Westergren method served as the reference standard; however, due to its recognised limitations, many laboratories have transitioned to alternate and/or modified automated methods [2]. These methods employ various technologies including centrifugation or photometric aggregometry to measure the ESR [3]. TEST1 (Alifax, Polverara, Italy) is a widely used alternate method in medium to high volume laboratories [4-8]. More recently, an upgraded version of the analyser (TEST1 2.0) has been introduced [9].
Quality control (QC) monitoring is essential for accurate and precise ESR measurement in clinical laboratories. Several studies have evaluated the performance of

the TEST1 1.0 analyzer and have consistently demonstrated improved precision as compared to the Westergren method [4-8]. This enhanced performance is attributed to the synthetic matrix of its control solution. Unlike other automated ESR methods that use stabilized human blood as control material, TEST1 employs latex-based controls [8]. To date, however, there are limited published studies evaluating the analytical performance of the upgraded TEST1 2.0 analyzer and its QC material. The present study therefore aimed to evaluate the TEST1 2.0 latex QC material for QC monitoring.

MATERIALS AND METHODS

Analyzer

TEST1 2.0 was calibrated with latex calibrators and the booster Y was aligned with the reference analyser. TEST1 2.0 is a closed, fully automated analyser that measures ESR at 37°C. A 150 µL blood sample flows through a capillary tube within the instrument. The diagnostic algorithm transforms the measurement performed within the first 20 seconds into photometric quantitative data. A mathematical algorithm converts the raw data transformed into comparable Westergren values, expressed in mm/hour [9]. The TEST1 2.0 provides a reportable range of 2 to 120 mm/hour. It accommodates EDTA samples in two modes: an internal mode for adult samples and an external mode for pediatric or short samples. The system dimensions are 77 cm in length, 74 cm in width, 86 cm in height, and it weighs 94 kg.

Standards

This study was performed in accordance with the Clinical and Laboratory Standards Institute (CLSI) and International Committee on Standardisation in Haematology (ICSH) [3,10]. This study was approved by the Human Research Ethics committee of the University of the Witwatersrand (Protocol number: M2410118).

Samples

The samples used for the verification included Latex Controls for TEST 1 (3 levels) (Alifax, Polverara, Italy). The expected ranges of each level were as follows: 6 - 11, 15 - 22 and 56 - 74 mm/hour. In addition, residual specimens referred for routine laboratory testing, which covered a wide range of normal and abnormal results of clinical relevance, were included. Aged and insufficient samples were excluded. Samples with a hematocrit value < 30% were also excluded. Samples were collected in K2EDTA or K3EDTA tubes (Vacutainer®, Becton Dickinson, Plymouth, UK) for analysis. Samples were stored at room temperature or 4 - 8°C and analyzed by a dedicated technologist within 12 or 24 hours of collection respectively. Daily QC measurements were performed.

Precision experiment

Within run precision was determined with patient samples and QC material in the normal and abnormal range each analyzed ten times during the same eight-hour period. Between-run precision was determined with QC material in the normal and abnormal range, analyzed three times a day on five consecutive days. This was performed in the internal and external mode. The manufacturer's % coefficient of variation (CV) for low, normal and high QC material were employed as the first hierarchy.

Internal quality control experiment

The statistical moving average was established following validation by analyzing the mean of 30 recent data points. A total of 300 ESR patient samples referred for routine analysis were included.

RESULTS

The results of the within-run and between-run precision analysis are presented in Tables 1. The within-run and between-run precision analysis at low, middle and high ESR levels was within the manufacturer's limits with QC material. The imprecision of the abnormal low and normal patient samples was high. However, this imprecision is clinically not significant as it covers the normal range. In contrast, the abnormal ESR patient sample which covers the clinically significant ESR range shows an acceptable imprecision of < 2.7%.

The ESR mean ± standard deviation (SD) was 68.0 ± 8.3 mm/hour. All data points were within 2SD of the mean with a % CV of 12.2% (Figure 1).

DISCUSSION

Most laboratories globally have transitioned to alternate ESR methods due to their numerous benefits [3]. Since introduction, automated ESR methods have consistently demonstrated improved precision, as compared to the manual Westergren method [2,8]. Cennamo et al. reported a strong between-run precision on the TEST1 1.0 using QC material, with CV's of 0%, 3.3%, and 2% for low, medium, and high ESR ranges, respectively [2]. The TEST1 1.0 also showed acceptable within run precision with patient samples, with a mean CV of 9% for ESR values > 20 mm/hour [2]. This study evaluated the bench-top TEST1 2.0 alternate ESR method in an adult and pediatric patient population. Similarly, the within run and between run precision of the TEST1 2.0 using latex-based QC material were excellent. Additionally, we assessed QC procedures using fresh EDTA-anticoagulated patient samples. While the precision of the abnormal low and normal patient samples was high, the precision for ESR values > 20 mm/hour, which covers the clinically significant ESR range, showed an acceptable imprecision of < 2.7% [9]. These findings support

Table 1. Precision analysis for normal, abnormal high and low control material and patient samples.

Control samples	Within-run precision control samples CV%			Manufacturer's acceptance criteria for precision CV%		
Parameter (n = 10)	abnormal control low	normal control	abnormal control high	low	normal	high
TEST1 2.0 external mode ESR, mm/h	0.00	0.00	0.69	7.52	3.28	2.70
TEST1 2.0 internal mode ESR, mm/h	0.0	2.79	1.03	7.52	3.28	2.70
Control samples	between-run precision control samples CV%					
Parameter (n = 25)	abnormal control low	normal control	abnormal control high	low	normal	high
TEST1 2.0 external mode ESR, mm/h	3.65	2.27	2.02	7.52	3.28	2.70
TEST1 2.0 internal mode ESR, mm/h	5.31	1.51	1.38	7.52	3.28	2.70
Patient samples	within-run precision patient samples CV%					
Parameter (n = 10)	abnormal low	normal	abnormal High	low	normal	high
TEST1 2.0 external mode ESR, mm/h	24.79	10.76	0.00	7.52	3.28	2.70
TEST1 2.0 internal mode ESR, mm/h	13.98	9.85	0.00	7.52	3.28	2.70

ESR: erythrocyte sedimentation rate, CV: coefficient of variation.

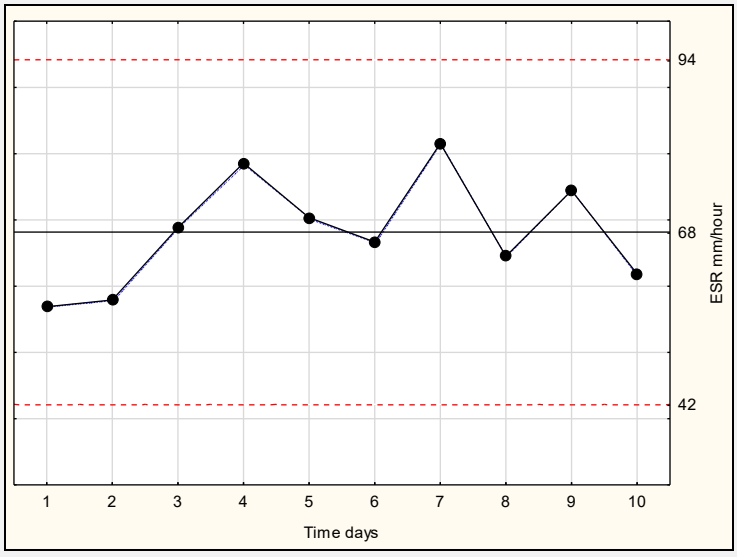


Figure 1. X-bar Chart Monitoring Daily Mean ESR values (mm/hour).

Each data point represents 30 ESR patient samples.

the reliability of the upgraded TEST1 2.0 system for routine ESR testing.

Guidelines recommend the use of commercial control materials and/or EDTA-anticoagulated patient samples for assessing precision of daily laboratory testing [3,10]. Several commercial QC materials are available. However, most are based on stabilized whole blood and are not compatible with the TEST1 2.0, which measures the kinetics of erythrocyte aggregation. A latex-based QC material has been specifically developed for use with the TEST1 system. Each QC set comprises three tubes containing 3 mL of latex solution at defined concentrations, each with a known turbidity value. These controls are readily available and user-friendly, making them a practical solution for daily laboratory QC. In addition to monitoring QC using latex QC materials, EDTA-anticoagulated patient samples were monitored. A moving average, calculated from consecutive patient sample results, was applied. The moving average is a patient-based statistical QC technique that can be applied to monitor ESR results in routine practice. With each new result, the average was updated, thereby generating a continuous “moving” statistic. Latex QC materials in conjunction with patient-based moving average monitoring provided a comprehensive, practical, and reliable QC strategy for the TEST1 2.0, ensuring consistent performance and analytical confidence in routine ESR testing.

A limitation of this study was that the moving average was assessed over a limited period; however, with ongoing monitoring, systematic errors such as a shift in the moving average may serve as an indicator of analytical errors, including reagent deterioration, calibration drift, or analyzer errors. Since ESR values are influenced by population-specific distributions, optimization is required prior to implementation. Strategies may include applying reference intervals, excluding abnormal results from specific clinical settings (e.g., rheumatology outpatients or infectious wards), or omitting referred samples with prolonged storage times. The current software version of the TEST1 2.0 analyzer does not provide functionality for QC plotting or monitoring. Consequently, laboratories must record results manually or rely on external software for daily QC monitoring. In conclusion, the TEST1 2.0 is an alternative method for ESR measurement that provides rapid and precise results. With software upgrades, the use of patient-based moving averages in conjunction with latex QC material is advised to enhance internal QC and support patient safety.

Declaration:

The authors declare the manuscript has not been published in whole or in parts nor submitted elsewhere.

All authors agree to the submission.

Declaration of Generative AI in Scientific Writing:

The authors declare that no generative AI tools were used in the preparation of this manuscript.

Declaration of Interest:

The author(s) declare no conflict of interests with respect to the authorship and/or publication of this article.

References:

1. Piva E, Sanzari MC, Servidio G, Plebani M. Length of sedimentation reaction in undiluted blood (erythrocyte sedimentation rate): variations with sex and age and reference limits. Clin Chem Lab Med 2001 May;39(5):451-4. (PMID: 11434396)

2. Cennamo M, Giuliano L, Arrigoni G, et al. Method Comparison of Erythrocyte Sedimentation Rate Automated Systems, the VES-MATIC 5 (DIESSE) and Test 1 (ALIFAX), with the Reference Method in Routine Practice. J Clin Med 2024 Feb 1;13(3):847. (PMID: 38337540)

3. Kratz A, Plebani M, Peng M, Lee YK, McCafferty R, Machin SJ; International Council for Standardization in Haematology (ICSH). ICSH recommendations for modified and alternate methods measuring the erythrocyte sedimentation rate. Int J Lab Hematol 2017 Oct;39(5):448-57. (PMID: 28497537)

4. Hardeman MR, Levitus M, Pelliccia A, Bouman AA. Test 1 analyser for determination of ESR. 1. Practical evaluation and comparison with the Westergren technique. Scand J Clin Lab Invest 2010 Feb;70(1):21-5. (PMID: 19929270)

5. Sonmez C, Dogan OC, Kaymak AO, Akkaya N, Akin KO, Guntas G. Test-1 analyzer and conventional Westergren method for erythrocyte sedimentation rate: A comparative study between two laboratories. J Clin Lab Anal 2018 Jun;32(5):e22384. (PMID: 29341286)

6. Pieri M, Pignalosa S, Perrone MA, et al. Evaluation of the Diesse Cube 30 touch erythrocyte sedimentation method in comparison with Alifax test 1 and the manual Westergren gold standard method. Scand J Clin Lab Invest 2021 May;81(3):181-6. (PMID: 33586554)

7. Chaiwong K, Naksith R, Laiklang W, et al. Three-way comparison of different ESR measurement methods and analytical performance assessment of TEST1 automated ESR analyzer. Diagnosis (Berl) 2024 Dec 12;12(2):268-76. (PMID: 39661722)

8. Cha CH, Cha YJ, Park CJ, et al. Evaluation of the TEST 1 erythrocyte sedimentation rate system and intra- and inter-laboratory quality control using new latex control materials. Clin Chem Lab Med 2010 Jul;48(7):1043-8. (PMID: 20459354)

9. Alifax (2021) TEST1 2.0 Instrument: User Manual. Polverara, Italy: Alifax S.r.l. https://www.manuallib.com

10. Clinical and Laboratory Standards Institute (CLSI). Procedures for the erythrocyte sedimentation rate test; approved standard fifth edition. CLSI document H02-A5. Wayne, PA: CLSI; 2011. https://clsi.org